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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,100	06/01/2001	Reinhold Schmieding	P/1493-406	2429

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EXAMINER

DEMILLE, DANTON D

ART UNIT

PAPER NUMBER

3764

DATE MAILED: 09/15/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/872,100

Applicant(s)

SCHMIEDING, REINHOLD

Examiner

Danton DeMille

Art Unit

3764

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION***Claim Rejections - 35 USC § 103***

Claims 1-4 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti in view of Anderson et al. Bonutti teaches the method of correcting a deformity by resecting the bone, opening the resection, packing the resection with a wedge shaped section of material 36 and placing a bone plate 62 spanning the open resection. While Bonutti may not teach that the wedge shaped packing is not composed of a plurality of pieces, Anderson teaches just such a convention. Anderson teaches the bone grafts can be composed of a plurality of separate wedge shaped sections. It would have been obvious to one of ordinary skill in the art to modify Bonutti to use an implant that is composed of multiple separate sections as taught by Anderson to improve the strength of the implant.

Claims 9, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacMahon in view of Puddu '875. MacMahon teaches resecting the bone, opening the resection and packing the resection with cancellous bank bone or artificial bone material forming a wedge shape of material. A second separate wedge shaped section or implant 1 is also packed in the resection. While MacMahon may not teach the advantage of using a wedge shaped tool to help open the resection, Puddu teaches such a convention. It would have been obvious to one of ordinary skill in the art to modify MacMahon to use a wedge to open the resection as taught by Puddu to help open the resection in a more precise and measured amount.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 14 above and further in view of Urist. MacMahon teaches that the packing material can comprise any number of conventional materials including cancellous

bank bone and artificial bone materials as well as direct bone grafts, column 8 lines 1-17.

Clearly any conventional material could be used as taught by MacMahon. Urist teaches the advantages of using biodegradable polylactic acid polymer for use in making implants, plates, screws and all kinds of orthopedic reconstructive operations, column 5, lines 18-21. "Either purified BMP or its co-precipitate with tricalcium phosphate may be used." (column 4, lines 2-4)

It would have been obvious to one of ordinary skill in the art to further modify MacMahon and use an artificial bone material including biodegradable polylactide combined with tricalcium phosphate as taught by Urist to greatly increase the amount of new bone growth.

Allowable Subject Matter

Claims 10-12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 30 June 2003 have been fully considered but they are not persuasive. Applicant argues that "Bonutti discloses a method in which the wedge member itself opens the resection and remains in place in the tibia." This may be true however, there is no claim language in claim 1 that would somehow define over this method. The claim recites "opening the resection to a height at which the deformity is corrected" this is what the wedge member does. It opens the resection to a height which the deformity is corrected. This step in Bonutti also provides the step of packing the open resection with at least one wedge shaped section of material. Bonutti also teaches the implant 1 "is preferably secured by means of a small screw 13 driven into the tibia through the fixation tab 11." Alternatively, "a bone plate can

be attached to the tibia over the medial surface of the implant to hold it in place during healing and bone growth” (column 8, lines 50-56) This would comprehend the claimed “placing the bone plate in a location such that the bone plate spans the open resection”. Bonutti teaches all of the steps claimed with the exception of the wedge shaped graft comprises two separate wedge shaped sections.

Bonutti teaches that the wedge shaped section of material “may be formed of any one of many different known materials.” The graft may be formed from bone or stainless steel, for example. Anderson teaches the advantage of using a bone graft that is composed of at least two separate wedge shaped sections of material. Anderson is not cited to teach all of the other limitations of the claims because Bonutti does that. Anderson is merely cited to teach that bone grafts can be composed to at least two separate sections of material secured together so that large sections of bone material can be used to form the graft and still have adequate mechanical strength.

It is not an inventive step to merely replace the composition of one bone graft with another. All one has to do is replace the wedge shaped graft of Bonutti with the wedge shaped graft of Anderson to anticipate the claims.

Regarding claims 9-15, adding the step of using a wedge tool to help open the resection is not new. Puddu teaches this convention. Using a wedge to drive the two sections of bone apart would have been an obvious provision in MacMahon.

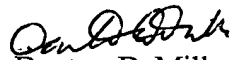
Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

ddd
10 September, 2003
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Danton DeMille
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Art Unit 3764